JUN 2 3 2000

510(k) SUMMARY K000906

Applicant:

Mölnlycke Health Care
500 Baldwin Tower
Eddystone, PA 19022

Contact Person:

Miguel A. Negron
Manager, Regulatory Affairs & Quality
North America
Tel.: 610-499-3383
Fax: 610-499-3415

Device Name:

Proprietary Name:	Klinidrape® Surgical Drapes
Common/Usual Name:	Surgical Drapes
Device Classification:	Class II – 21 CFR 878.4370

Substantial Equivalence:

For the purpose of Section 510(k) of the Federal Food, Drug and Cosmetic Act, Mölnlycke Health Care considers the Klinidrape® Surgical Drapes are substantially equivalent in composition, function and intended use to Convertors® Trilaminate Drapes.

Intended Use:

The Klinidrape® Surgical Drapes are devices intended to be used as a protective patient covering, such as to insolate a site of surgical incision from microbial and other contamination.

Description:

The Klinidrape® Surgical Drapes are composed of a 3-laminate or 2-laminate layers containing nonwoven, polyethylene film and/or white tissue.

Summary of Testing:

The Klinidrape® Surgical Drapes have been found non-toxic and non-irritant when tested by the above biological tests in accordance with the ISO 10993, Part I, "Biological Evaluation of Medical Devices". The Klinidrape® Surgical Drapes have been tested for their fluid barrier properties in accordance with Suter Hydrostatic Testing AATCC 127-98 and Mullen Hydrostatic Pressure Testing ASTM D751-95.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2000

Mr. Miguel A. Negron
Manager, Regulatory Affairs & Quality
North America
MÖInlycke Health Care
500 Baldwin Tower
Eddystone, Pennsylvania 19022

Re: K000906
Trade Name: Klinidrape® Surgical Drapes
Regulatory Class: II
Product Code: KKX
Dated: May 30, 2000
Received: May 31, 2000

Dear Mr. Negron:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: Unassigned K000906

Mölnlycke Health Care

Device Name: Klinidrape® Surgical Drapes

Indications for Use:

The Klinidrape® Surgical Drapes are devices intended to be used as a protective patient covering, such as to insolate a site of surgical incision from microbial and other contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ Or Over-The-Counter Use X
(Per 21 CFR 801.109)

Olivia S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000906